

CLAIMS

1. Virally-safe plasma-derived Factor VIII composition, characterized in that it is obtained after filtering through a nanometric filter of nominal pore size 15 ± 2 nm to 23 ± 2 nm, and in that its von Willebrand Factor (vWF) content is 15 % or less of decamers and higher multimers.

2. Composition as in claim 1, characterized in that the titre reduction factor of a virus of size 27 ± 3 nm is 4 log or more, preferably 5 log, advantageously 6 log compared with the solution before filtration.

3. Pharmaceutical composition as in either of claims 1 and 2 in the form of an injectable solution via intravenous, intramuscular or subcutaneous route.

4. Method for testing the viral safety of a plasma-derived Factor VIII composition obtained by nanometric filtering, comprising a step consisting of determining the residual content of high multimerisation vWF.

5. Method as in claim 4, characterized in that the detection of less than 15 % vWF decamers and higher multimers after nanometric filtration indicates that said composition is virally safe.

6. Method as in claim 5, characterized in that the detection of less than 15 % vWF decamers and higher multimers is correlated with a reduction factor of virus titre of at least 4 log.

7. Method for preparing a virally safe Factor VIII solution comprising a filtering step through nanometric filters of nominal pore size 15 ± 2 nm to 23 ± 2 nm, and an assay step of von Willebrand Factor (vWF) decamers and higher multimers.

8. Method as in claim 7, characterized in that the assay step consists of verifying that the content of vWF decamers and higher multimers is 15 % or less.

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9. Method as in claim 7, characterized in that a vWF decamer and higher multimer content of 15 % or less indicates that the titre reduction factor of a virus of size 27 ± 3 nm is 4 log or more, preferably 5 log or 6 log.

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10. Use of a composition as in any of claims 1 to 3 or of a Factor VIII solution obtained using the method as in any of claims 7 to 9, to prepare a medicinal product intended to treat diseases related to blood coagulation, haemophilia in particular.

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